

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effectiveness of the gluten free diet and gluten containing diet on gastrointestinal and behavioral indices for children with Autism Spectrum Disorders

Protocol summary

Summary

In this study, 80 children diagnosed with Autism spectrum Disorders attending the rehabilitation center for children with ASD are going to be studied. The aim of this study is to determine the effect of gluten free diet intervention on ASD and gastrointestinal symptoms. Inclusion criteria consist of: patients diagnosed with ASD, age between 4-16 years, also the exclusion criteria are: healthy children not diagnosed with ASD and unwilling to participate in the study. Participants will be divided into two groups of 40. One group will be achieving 200 g gluten free grains and the second group will receive 200 g grains containing gluten in the duration of 6 weeks intervention. At the baseline and at the end of the study a demographic questionnaire, GARS-2 and a questionnaire for evaluating gastrointestinal symptoms will be completed by interviewing parents. Also anthropometric measures including weight, height and BMI will be calculated and assessed. Additionally 5 ml blood sample will be taken after a night fasting by a laboratory technician at the rehabilitation center for children with ASD, in the beginning and at the end of the intervention. The blood samples will be centrifuged and stored at -80° C. Anti-tissue transglutaminase IgA antibodies (tTGA) will be analyzed by chemiluminescence immunoassay system and total serum IgA levels will be analyzed by nephrometry scoring system.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404212017N20**
Registration date: **2014-05-27, 1393/03/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-27, 1393/03/06

Registrant information

Name

Alireza Ostadrahimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Email address

ostadrahimi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of the gluten free diet and gluten containing diet on gastrointestinal and behavioral indices for children with Autism Spectrum Disorders

Public title

The effect of gluten free diet on gastrointestinal and behavioral indices in children with ASD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients diagnosed with ASD ; age between 4-16 years; capable of eating food; willing to participate in the study
Exclusion criteria: children without ASD; pursuing a particular diet; unwilling to participate in the study

Age

From **4 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences

Street address

Attar Alley, Golgasht Street, Tabriz University of Medical Sciences, Tabriz, Iran

City

Tabriz

Postal code

Approval date

2014-04-14, 1393/01/25

Ethics committee reference number

937

Health conditions studied

1

Description of health condition studied

Childhood Autism

ICD-10 code

F84.0

ICD-10 code description

Childhood Autism

Primary outcomes

1

Description

Behavioural Symptoms

Timepoint

Before and After 6 Weeks Intervention

Method of measurement

Gilliam Autism Rating Scale Questionnaire

2

Description

Gastrointestinal Symptoms

Timepoint

Before and After 6 Weeks of Intervention

Method of measurement

Shahid Beheshti Questionnaire for Gastrointestinal Symptoms

3

Description

Tissue Transglutaminase Immunoglobulin A

Timepoint

Before and after 6 weeks of intervention

Method of measurement

Chemiluminescence Immunoassay System

4

Description

Immunoglobulin A

Timepoint

Before and after 6 weeks of intervention

Method of measurement

Nephrometry

Secondary outcomes

1

Description

Body Mass Index

Timepoint

Before and after 6 weeks of intervention

Method of measurement

Weight/Height*2

Intervention groups

1

Description

Gluten Free Diet: Gluten free bread, biscuit, pasta

Category

Lifestyle

2

Description

Gluten containing diet: Regular bread, biscuit, pasta

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized treatment and rehabilitation center for children with pervasive developmental disorder

Full name of responsible person

Faezeh Ghalichi

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Bahram Poor gaseme Gargari

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Attar Alley, Golgasht Street, Tabriz University of Medical Sciences, Tabriz, Iran

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Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostadrahimi

Position

PHD in Nutrition Sciences

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty